

Message Text

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INFORM CONSULS

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SUBJECT: PENDING U.S. BAN ON USE OF SACCHARIN IN FOOD,
BEVERAGES, UGS, AND COSMETICS

REF: (A) STATE 57630, (B) STATE 55170

1. FOR THE INFORMATION OF THE POSTS AND TRANSMITTAL TO
HOST GOVERNMENTS IF APPROPRIATE, THE DEPARTMENT IS TRANS-
MITTING AN ABBREVIATED VERSION OF A FOOD AND DRUG
ADMINISTRATION PRESS RELEASE OF APRIL 14 ON ITS PROPOSAL
REGARDING ITS PLANS FOR REGULATION OF SACCHARIN. BEGIN
ABBREVIATED VERSION OF PRESS RELEASE:

THE FOOD AND DRUG ADMINISTRATION ON APRIL 14 ISSUED
FOR PUBLIC COMMENT A DETAILED PLAN FOR ENDING THE USE OF
ARTIFICIAL SWEETENER SACCHARIN AS A GENERAL PURPOSE FOOD
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ADDITIVE. THIS ACTION FULFILLS A MARCH 9 COMMITMENT BY
THE AGENCY TO INITIATE ACTION TO BAN SACCHARIN IN FOODS
AND BEVERAGES (SEE REFS).

FDA ALSO PROPOSED TO PERMIT THE CONTINUED MARKETING OF
SACCHARIN AS A SINGLE-INGREDIENT DRUG FOR USE BY DIABETICS
AND OTHERS WHO, FOR MEDICAL REASONS, MUST RESTRICT THEIR

INTAKE OF SUGAR AND OTHER NUTRITIVE SWEETENERS.

IN ADDITION, FDA'S PROPOSAL WOULD BAN SACCHARIN IN COSMETICS THAT ARE LIKELY TO BE INGESTED SUCH AS TOOTH-PASTES AND MOUTHWASHES, AND AS A NON-MEDICAL INGREDIENT IN DRUGS, FOR EXAMPLE WHEN USED TO MAKE DRUGS TASTE BETTER.

FDA IS ACTING ON THE BASIS OF ACCUMULATED SCIENTIFIC EVIDENCE WHICH SHOWS THAT SACCHARIN CAUSES BLADDER CANCERS IN TEST ANIMALS AND, THEREFORE, INDICATES AN INCREASED RISK OF BLADDER CANCER IN HUMANS. THE LEGAL BASES FOR THE PROPOSED ACTIONS ARE THE GENERAL SAFETY STANDARD OF THE FOOD ADDITIVES AMENDMENT OF THE FOOD, DRUG AND COSMETIC ACT, AS WELL AS THE SPECIFIC REQUIREMENTS OF THE DELANEY CLAUSE.

UNDER THE PROPOSALS ANNOUNCED APRIL 15:

--SACCHARIN WOULD BE BANNED AS AN INGREDIENT IN FOODS AND BEVERAGES, BEGINNING WITH PUBLICATION OF A FINAL REGULATION. AFTER THE FINAL REGULATION IS PUBLISHED, SACCHARIN COULD NOT BE ADDED TO ANY FOOD BY MANUFACTURERS. FULLY-PROCESSED FOODS AND BEVERAGES CONTAINING SACCHARIN WHICH HAD BEEN MADE BEFORE THE BAN COULD BE SOLD. THERE WOULD BE NO RECALL.

THIS ACTION WILL BAN MOST CURRENT USES OF SACCHARIN, SUCH AS ITS USE IN DIET SODAS AND OTHER ARTIFICIALLY-SWEETENED FOODS.

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--SACCHARIN WOULD BE PERMITTED TO BE SOLD WITHOUT A PRESCRIPTION AS A SINGLE-INGREDIENT DRUG, PROVIDED MANUFACTURERS CAN DEMONSTRATE IT IS EFFECTIVE IN MEDICAL USES SUCH AS THE MANAGEMENT OF DIABETES OR IN WEIGHT CONTROL PROGRAMS. MANUFACTURERS WILL BE GIVEN 180 DAYS AFTER THE FINAL REGULATION TO SUBMIT THE NECESSARY DATA.

SACCHARIN WOULD CONTINUE TO BE SOLD FOR DRUG USES WHILE THE DATA TO JUSTIFY PERMANENT DRUG USE ARE BEING EVALUATED. DURING THIS EVALUATION PERIOD, LABELS OF ALL SINGLE-INGREDIENT SACCHARIN PRODUCTS WOULD HAVE TO STATE: "FOR USE AS A NON-CALORIC SWEETENER WHEN SUGAR-RESTRICTED DIETS ARE MEDICALLY INDICATED, AS IN PATIENTS WITH DIABETES" AND "WARNING: SACCHARIN CAUSES BLADDER CANCER IN ANIMALS. USE OF SACCHARIN MAY INCREASE YOUR RISK OF CANCER."

--SACCHARIN WOULD BE BANNED AS A NON-MEDICAL INGREDIENT

IN DRUGS. MANUFACTURERS WOULD HAVE 15 MONTHS AFTER A

FINAL REGULATION IS ISSUED TO DISCONTINUE SUCH USES OF THE ARTIFICIAL SWEETENER, PLUS AN ADDITIONAL THREE MONTHS TO DISPOSE OF EXISTING STOCK.

FDA WILL CONSIDER REQUESTS TO PERMIT THE CONTINUED USE OF SACCHARIN AS AN INGREDIENT IN DRUGS ESPECIALLY FORMULATED FOR DIABETICS, BUT ONLY IF THE MANUFACTURER SUBMITS DATA DEMONSTRATING THE MEDICAL NEED FOR SUCH USE.

--SACCHARIN WOULD BE BANNED AS AN INGREDIENT IN COSMETICS LIKELY TO BE INGESTED, SUCH AS LIPSTICKS, TOOTHPASTES AND MOUTHWASHES 30 DAYS AFTER PUBLICATION OF A FINAL REGULATION. AFTER THAT TIME, SACCHARIN COULD NOT BE ADDED TO ANY COSMETIC BY A MANUFACTURER. COSMETICS UNCLASSIFIED

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ALREADY CONTAINING SACCHARIN COULD BE SOLD.

WHILE FDA WAS DRAFTING THE DOCUMENTS NECESSARY TO PROPOSE FORMALLY THE BAN ON SACCHARIN IN FOODS AND BEVERAGES, IT ALSO ADDRESSED ITSELF TO THE ISSUE OF SACCHARIN'S USE IN COSMETICS AND DRUGS. THE LAWS APPLICABLE TO THESE PRODUCTS DIFFER FROM THE FOOD LAW.

FOR DRUGS, THE LAW PERMITS FDA TO MAKE JUDGMENTS AS TO WHETHER THE BENEFIT OF A PRODUCT OUTWEIGHTS THE RISKS. FOR FOOD USES, THE LAW ALLOWS NO SUCH JUDGMENTS.

THE PROPOSED REGULATIONS ON SACCHARIN WERE PUBLISHED IN THE FEDERAL REGISTER APRIL 15, 1977. COMMENTS MAY BE SENT WITHIN 60 DAYS TO HEARING CLERK, FOOD AND DRUG ADMINISTRATION, ROOM 4-65, 5600 FISHERS LANE, ROCKVILLE, MARYLAND 20857. COMMENTS SHOULD BE PROMINENTLY MARKED "SACCHARIN." FDA WILL HOLD A PUBLIC HEARING IN WASHINGTON ON MAY 18 AND 19.

FINAL REGULATIONS WILL BE ISSUED AFTER FDA EVALUATES THE COMMENTS AND THE HEARING RECORD. FINAL REGULATIONS, COMPLETE WITH EFFECTIVE DATES, ARE EXPECTED TO BE PUBLISHED THIS SUMMER. END ABBREVIATED VERSION OF PRESS RELEASE.

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